

## **REMARKS**

### **Amendment**

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Claims 1-3 remain in this application. Claim 1 has been allowed. Claim 3 has been cancelled. Claims 2 and 3 remain rejected. This rejection is respectfully traversed.

### **The 35 USC §112 Rejections**

Claims 2 and 3 stand rejected under 35 USC §112, first paragraph, as unenabled. This rejection is respectfully traversed.

The Examiner continues to reject claims 2 and 3 as unenabled for the localized expression of genes in a host organism, continuing to cite Crooke ("Principles of Antisense Therapeutics," In: Antisense Research and Application, Springer-Verlag, 1998, pp. 1-50) describing current difficulties in gene therapy. However, claim 2

does not necessarily have to relate to gene therapy. Instead, claim 2 recites that the gene is inserted into the cloning site of the pDATH-X vector, which is then introduced into the host organism. As worded, claim 2 can be interpreted to relate to a gene inserted into a host organism at any time. This includes a transgene inserted into a zygote to form a transgenic animal. Various method of forming transgenic animals in this manner are well known in the art and thus enabled. In this case, the gene would be delivered to all cells of a host organism but only induced locally by heat in a tetracycline-treated organism. While claim 2 can also be interpreted to apply to gene therapy, which may become enabled as the result of future developments in the art, the claim does not require that the instant invention only be used for gene therapy. Therefore, claim 2 is in fact enabled.

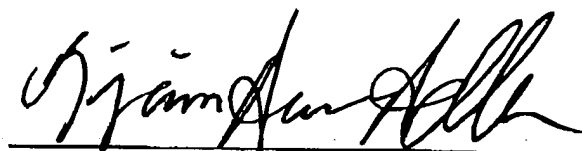
The Examiner also continues to argue that variation in the pharmacokinetics of tetracycline delivery is one of the uncertainties of the instant invention. If were indeed a problem, it would not be possible to systemically administer tetracycline to fight localized bacterial infections. However, it is well known in the art to that

tetracycline can be systemically administered for this purpose. Therefore, systemic administration of tetracycline for purposes of inducing gene expression should not pose any addition difficulties over systemic administration to fight bacterial infection. The Applicants respectfully request that the 35 USC §112, first paragraph rejection of Claims 2 and 3 as unenabled be withdrawn.

This is intended to be a complete response to the Final Office Action mailed April 9, 2001. The Applicants submit that the pending claims are in condition for allowance. If any issues remain, please telephone the attorney of record for immediate resolution.

Respectfully submitted,

DATE: June 5, 2001



Benjamin Aaron Adler, Ph.D., J.D.  
Registration No. 35,423  
Counsel for Applicant

ADLER & ASSOCIATES  
8011 Candle Lane  
Houston, Texas 77071  
(713) 270-5391  
badler1@ houston.rr.com

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Please cancel claim 3.